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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Part of Paper No./Mail Date 02172006

DETAILED ACTION

Preliminary Amendment

1. Acknowledgment is made of applicant's amendment, which was received by the Office on January 15, 2004.

Priority

2. Acknowledgment is made of applicant's claim for priority filing as a Continuation of U.S. Application Serial No. 10/036,340, filed December 24, 2001, now U.S. Patent No. 6,708,064, which is a Continuation-In-Part of U.S. Application Serial No. 09/511,842, filed February 24, 2000, now U.S. Patent No. 6,609,030, and is also a Continuation-In-Part of U.S. Application Serial No. 09/511,843, filed February 24, 2000, now U.S. Patent No. 6,418,344, and is also a Continuation-In-Part of U.S. Applications 09/511,844, 09/511,845, 09/575,292, 09/575,293, and 09/574,495, all now Abandoned.

3. Although the applicant claims priority filing back to February 24, 2000, after a careful review of the '030 patent, the Examiner has concluded that priority for the claimed subject matter does not predate the December 24, 2001 priority filing date since the concept of "sensing activity" was first recited in what is now the '064 patent.

Drawings

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4. Applicant's formal drawings were received by the Office on January 15, 2004 and have been approved by the Examiner.

Specification

5. The disclosure is objected to because of the following informalities:

-p.1, first paragraph, lines 1-4, please update the status of the following cases to reflect the fact that they are now patents:

Application 10/036,340 is now U.S. Patent No. 6,708,064

Application 09/511,842 is now U.S. Patent No. 6,609,030

Application 09/511,843 is now U.S. Patent No. 6,418,344

Also update the following cases to reflect the fact that they are now abandoned:

Applications 09/511,844, 09/511,845, 09/575,292, 09/575,293, and 09/574,495

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 15, there is no antecedent basis in the claim language for the recitation of "the electrode" (line 2). To overcome this rejection, the Examiner recommends changing the words "the electrode" to "an electrode".

In regard to claim 25, the claim is indefinite in that it is unclear what is meant by the acronym "ILN". To overcome this rejection, the Examiner recommends defining the first instance of this by substituting the words "intralaminar nuclei (ILN)" for the acronym "ILN".

In regard to claim 29, the claim is indefinite in that it is unclear what is meant by the acronym "ELN". Is this a typo?? To overcome this rejection, the Examiner recommends writing out what this means prior to its first use.

Claims 26-28 and 30 are also rejected since they depend from a rejected base claim.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1, 2, 4-7, 11, 14, 16-23, and 25-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 4-8, 14, 16-23, and 25-30, respectively, of copending Application No. 10/329,285. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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10. Claims 25-29 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15-19, respectively, of prior U.S. Patent No. 6,708,064. This is a double patenting rejection.

11. Claims 1, 3, 4, 12-18, 20, 21, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-14, respectively, of U.S. Patent No. 6,708,064. Although the conflicting claims are not identical, they are not patentably distinct from each other because both recite the same method steps of “implanting”, “sensing activity”, and “operating”. The only difference between the claim sets is the recitation in claim 1 of the ‘064 patent that the step of “sensing activity” does not occur in the intralaminar nuclei (ILN) of the brain. Hence, the claims of the ‘064 patent represent a subset of those being claimed in this application.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 1-5, 9-11, 14-20, 23, 25, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by John (US 6,066,163).

The John (US 6,066,163) patent describes an adaptive deep brain stimulation method and system (Fig.1) whose operation appears to read upon applicant's claimed method steps. Specifically, John discloses that its implantable stimulation electrodes **50,78** (Fig.4) may be used to stimulate appropriate areas of the brain including, among other regions, the intralaminar nuclei (col.5, lines 33-35). Both scalp electrodes **12a** and an implantable sensor electrode **82** (Fig.4) are used to sense physiological data of the brain (col.10, lines 43-46). Lacking specifics, the Examiner considers the position of electrode **82** to be "distal" from the stimulating device location in the intralaminar nuclei. The stimulation device delivers electrical therapy to the intralaminar nuclei to treat a variety of brain disorders including brain injury and coma (Abstract, line 3).

In regard to claims 5 and 20, rather than use electrical stimulation, the deep brain stimulation device of John can, alternatively, use pharmacological injectors such as systemic injection or local microinjection of psychostimulants or other "functional agonists or antagonists" (col.12, lines 55-63). See infusion controller **88** (Fig.4).

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In regard to claims 9 and 10, the electric brain stimulation is produced according to a brain “specified reinforcement schedule” (col.3, line 38), which suggests an intermittent/periodic treatment.

In regard to claims 11, 14, and 23, brain electric activity may be sensed at a “specific area” on the patient’s scalp using electrodes **12a** (Fig.4).

14. Claims 1-5, 9-11, 14-20, 23, 25, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by John (US 6,463,328).

The John (US 6,463,328) patent describes a device which operates similarly to that of John ‘163, described above, in that it recites a deep brain stimulation (DBS) system (Fig.4) comprising stimulation electrodes 50,71,78 for stimulating the intralaminar nuclei (col.6, line 9), and sensing electrodes **12a** and **82** for obtaining physiological data from the brain (col.11, lines 51-54). Unlike John ‘163, this reference specifies alternative placements for sensing electrode **82** relative to stimulation electrode **50** – one of which may be considered “distal”. See Figs.4 and 7. The stimulation system of John ‘328 is used to treat disorders such as traumatic brain injury, coma, movement disorder (Abstract, lines 1-3), tremor (col.16, lines 45-64), or addiction (paragraphs [0022-0023]).

In regard to claims 5 and 20, rather than use electrical stimulation, the deep brain stimulation device of John can, alternatively, use pharmacological injectors such as systemic injection or local microinjection of psychostimulants or other “functional agonists or antagonists” (col.11, line 60 thru col.12, line 34). See infusion controller **88** (Figs.4 and 7).

In regard to claims 9 and 10, the electric brain stimulation is produced according to a brain “specified reinforcement schedule” (col.3, line 60-63), which suggests an intermittent/periodic treatment.

In regard to claims 11, 14, and 23, brain electric activity may be sensed at a “specific area” on the patient’s scalp using electrodes **12a** (Fig.4).

Allowable Subject Matter

15. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO
PRIMARY EXAMINER

CHL
2/18/2006